# Quality Procedure Interim Change Notice (ICN)

| Section 1: Description of Change (Requestor completes) | 1. Document Catalog No.: ER2001-0480 |
|---|---|

| 2. QP No.:04.01 | 3. Revision/Interim Change No.: (current)<br><br>Revision 4, ICN #1 | 4. QP Title: Quality Procedure Development |
|---|---|---|

5. Description of Change (Attach marked-up pages if necessary) Add to section 6.6, Format: 6.6.14 When revising a quality procedure, the **author** shall ensure a revision indicator (e.g., revision side bar) is entered in the left margin adjacent to the revised text.

Add to section 9.0 the following: (2 pages), located at http://erinternal.lanl.gov/Quality/forms.htm.

6. Attachments Modified, Added, or Removed:  ☐ Yes       X No

7. Justification for ICN: This change will enable ER Project personnel in completing their required training (e.g., reading only those sections that have been revised).

| 8. Requestor | Andrew E. Gallegos | Signature on File | June 4, 2001 |
|---|---|---|---|
|  | print name, then sign |  | (Date) |

| Section 2: Evaluation and Approval (QPPL and the Focus Area Leader completes) |
|---|

9. Evaluation Remarks: (If none enter N/A)

| 10. Focus Area Leader | N/A |  |
|---|---|---|
|  | print name, then sign | (Date) |

| 11. QPPL | Larry Maassen | (Signature on File) | 6/4/01 |
|---|---|---|---|
|  | print name, then sign |  | (Date) |

QP-04.01

Los Alamos
Environmental Restoration Project

| Identifier: | Revision: | Effective Date: |
|---|---|---|
| **QP-04.01** | **4** | **5/9/01** |

ER Document Catalog Number:  **ER2001-0047**

Author: Andrew E. Gallegos

**environmental restoration project**

Environmental Restoration Project
Quality Procedure

for:

# Quality Procedure Development

# Los Alamos

NATIONAL LABORATORY

Los Alamos, New Mexico  87545

# Revision Log

| Revision No. | Effective Date | Prepared By | Description of Changes | Affected Pages |
|---|---|---|---|---|
| R0 | 2/23/98 | John L. Day | New Procedure. Replaces AP-01.1 and AP-01.5 | All |
| R1 | 2/23/98 | John L. Day | Format and process changes | All |
| R2 | 8/21/98 | John L. Day | Format and process changes | All |
| R3 | 8/24/99 | John L. Day | Format and process changes | All |
| R4 | 5/09/01 | Andrew E. Gallegos | Revised to incorporate revision log page, section 2.0 Scope, section 3.0 References, new sections to address Interim Change Notices, lessons learned, PAAA and ISM requirements and periodic procedure review requirements. | All |
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# Quality Procedure Development

## Table of Contents

# Quality Procedure Development

## 1.0 PURPOSE

This Quality Procedure (QP) states the responsibilities and describes the process for preparing, reviewing, approving, revising, and deleting the ER Project's QPs.

**Note:** These activities with regard to Standard Operating Procedures (SOPs) are covered in QP-04.02, Standard Operating Procedures Development.

## 2.0 SCOPE

This QP is a mandatory document and shall be implemented by all ER Project participants when developing, maintaining, reviewing or requesting changes to QPs for the ER Project.

## 3.0 REFERENCES

3.1 ER Project personnel should become familiar with the contents of the following documents to properly implement this QP.

- ER Project Quality Management Plan at http://erinternal.lanl.gov/home _links/Library_proc.htm.

- QP-02.02, Personnel Orientation and Training

- QP-03.02, Lessons Learned

- QP-03.05, Peer Review Process

- QP-04.02, Standard Operating Procedures Development

- QP-04.04, Record Transmittal to the Records Processing Facility

- QP-04.05, Document Control

- QP-04.09, Document Development and Approval Process: Peer Review Required

- Los Alamos National Laboratory Integrated Safety Management Description Document, #LAUR-98-2837

- Price Anderson Amendments Act

## 4.0 DEFINITIONS

4.1 *Effective date* — The first date that a particular revision of a document is to be used to perform work. The Document Control Coordinator (DCC) enters it on the cover page and the revision log page, before issuance.

4.2 *Interim Change Notice* — A method of revising a SOP to meet current work processes and/or requirements where the changes are typically of a more narrow scope than a complete revision. An interim change notice is reviewed only by those affected by the change.

4.3 *Major revisions* — Changes to a procedure that affect the technical content or process of the work.

4.4 *Minor revisions* — Editorial changes to a QP (that is, grammar or spelling corrections, renumbering sections or attachments, changing the title or document number, or updating organizational changes, etc.) that do not affect the technical content or process of the work.

4.5 *Quality procedure* — A document that describes the process for performing activities governed by the ER Project's *Quality Management Plan*.

## 5.0 RESPONSIBLE PERSONNEL

The following personnel are responsible for activities identified in Section 6.0 of this procedure.

5.1 ER Program Manager

5.2 Quality Program Project Leader (QPPL)

5.3 Focus Area Leader

5.4 ER Project Web Master

5.5 Author — The technical expert who owns the process described within the QP. The author may delegate the writing of the QP to another individual, but retains the ultimate responsibility for the QP's technical content.

5.6 Document Control Coordinator

5.7 Requester of a QP action — Anyone on the ER Project who requests the development of a new QP, revision of an existing QP, or deletion of an existing QP.

5.8 ER Project Participants

## 6.0 PROCEDURE

**Note:** Subcontractors performing work under the ER Project's quality program may follow this standard operating procedure (SOP) for developing standard operating procedures or may use their own procedure(s) as long as the substitute meets the requirements prescribed by the ER Project Quality Management Plan, and is approved by the ER Quality Program Project Leader (QPPL) before the commencement of the designated activities.

**Note:** ER Project participants may produce paper copies of this procedure printed from the controlled-document electronic file located [at http://erinternal.lanl.gov/home _links/Library_proc.htm](at http://erinternal.lanl.gov/home _links/Library_proc.htm). However, it is their responsibility to ensure that they are trained to and utilizing the current version of this procedure. The author may be contacted if text is unclear.

6.1     Prior to QP development and/or revision the **author** shall review the Los Alamos National Laboratory Integrated Safety Management Description Document, #LAUR-98-2837 (located at [http://www.lanl.gov/orgs/ism/ pdfs/desc_doc.pdf](http://www.lanl.gov/orgs/ism/pdfs/desc_doc.pdf)), and the Price Anderson Amendments Act, (located at [http://aea.genlaw.lanl.gov/PAAA/index.html](http://aea.genlaw.lanl.gov/PAAA/index.html)) to ensure applicable quality and safety requirements are addressed in the QP.

6.2     QP Action Request

6.2.1     The **requester** notifies the QPPL to request a QP action (e.g., development of a new QP, revision of an existing QP, or deletion of an existing QP). Any individual who works on the ER Project may request a QP action, and the request does not need to be done formally (e.g., an informal e-mail or phone call is sufficient).

6.2.2     If the requested action is a minor revision to an existing QP, proceed to Section 6.3.

6.2.3     If the requested action is a major revision to an existing QP or a development of a new QP, proceed to Section 6.4.

6.2.4     If the requested action is a QP deletion, proceed to Section 6.9.

6.3     Minor Revisions to Existing QPs

6.3.1     The **QPPL** or **author** revises the QP to incorporate the minor revisions and increments the revision number by one whole integer.

6.3.2     The **QPPL** or **author** sends both a hard copy and an electronic copy of the revised QP to the DCC.

6.3.3     The **DCC** processes the revised QP in accordance with QP-04.05, Document Control and completes the process as defined in Section 6.8.

6.4     Major Revisions to Existing QPs or QP Development

6.4.1     The **QPPL** assigns an author.

6.4.2     For the development of a new QP, the **author** contacts the DCC to obtain a unique identifier (e. g., QP-07.01).

**Note:**     An existing QP will already have an identifier.

6.4.3     The **author** acquires and completes a Document Catalog Number (in accordance with QP-04.09), by initiating the ER Project Document

Signature Form (located on the ER Project internal homepage http://erinternal.lanl.gov).

6.4.4 The **author** develops a draft of the QP that follows the format of the QP template as described in Section 6.6 and including the following:

- It must include the note as shown just above Section 1.0 of this QP and have nine sections numbered 1.0–9.0 with the same titles as the ones in this QP.

- The revision will be "R0" for a new QP and incremented by one digit for a revision to an existing QP (e.g., a "R0" would become "R1").

- If forms are used with a QP, they must also include the QP identifier.

6.4.5 The **author**, if appropriate works with an editor assigned to their focus area/organization to ensure that the QP is readable, coherent, and adheres to ER Project and Laboratory document-publication guidelines.

6.5 Interim Change Notice

6.5.1 Prior to initiating an Interim Change Notice (ICN), the **requestor** shall confirm with the author and/or the responsible Focus Area Leader to determine if an ICN is required.

6.5.2 The **requestor** acquires and completes a Document Catalog Number (in accordance with QP-04.09), by initiating the ER Project Document Signature Form The **requestor** shall ensure that no more than 2 ICNs have been issued against a procedure revision.

6.5.3 The **requestor** shall complete an ICN form (see Attachment A located at http://erinternal.lanl.gov/Quality/forms.htm). A justification for the ICN must be included and be consistent with the definition in Section 4.2.

6.5.4 The **requestor** shall obtain a review and concurrence by at least one technical reviewer and the QPPL. This review shall consider the changed portion of the procedure and the effects of the changes on the procedure.

6.5.5 After the ICN has been reviewed and approved, the **QPPL** shall forward an electronic and hard copy to the DCC for processing (Proceed to Section 6.8).

6.6 QP Format

A template for developing QPs is provided on the ER Project Intranet at: http://erinternal.lanl.gov/home_links/Library_proc.htm. This template provides the proper paragraph formatting, text that both demonstrates how

the different sections will look and how to properly accomplish the formatting, and the standard text for the introductory paragraphs for the different sections.

6.6.1 Cover Page

Include a cover page, which uses the format as provided in the QP template.

6.6.2 Revision Log

Include a revision log page, which lists the revision number, effective date, author's name, a brief description of the changes, and the affected pages.

6.6.3 Table of Contents

Include a table of contents which uses the format shown as provided in the QP template.

6.6.4 1.0 Purpose

Include a section that describes the process that the QP addresses

6.6.5 2.0 Scope

Include a section that defines the limits of the QP's applications regarding affected activities and organization (for clarity, specific exclusions may be stated). This section may also provide instructions for transition to the revised procedure.

6.6.6 3.0 References

Include a section that lists, by document number and title, the references cited in Sections 4.0 through 9.0. This section shall also include the following:

- ER Project personnel should become familiar with the contents of the following documents to properly implement this QP. **[Include this mandatory statement in all procedures]**

6.6.7 4.0 Definitions

Include a section that defines the terms, that are unique to the QP or terms that may be unfamiliar to the QP user. A glossary of definitions can be *located at [http://erinternal.lanl.gov/home_links/Library_proc.htm.](http://erinternal.lanl.gov/home_links/Library_proc.htm.)*

6.6.8 5.0 Responsible Personnel

Include a section that lists the individuals (by formal ER Project position title when appropriate) who have responsibilities in the QP.

6.6.9 6.0 Procedure

Include a section that briefly states the work process in clear and concise steps, giving one step per each numbered subsection. Identify the person (from Section 5.0, above) who performs each step. In addition, the following information must be included at the beginning of Section 6.0:

- Subcontractors performing work under the ER Project's quality program may follow this standard operating procedure (SOP) for developing standard operating procedures or may use their own procedure(s) as long as the substitute meets the requirements prescribed by the ER Project Quality Management Plan, and is approved by the ER Quality Program Project Leader (QPPL) before the commencement of the designated activities.

- ER Project participants may produce paper copies of this procedure printed from the controlled-document electronic file located at http://erinternal.lanl.gov/home_links/Library_proc.htm, however, it is their responsibility to ensure that they are trained to and utilizing the current version of this procedure. The author may be contacted if text is unclear.

6.6.10 7.0 Records

Include a section that states who is responsible for record submittal and list the records that are generated by the QP.

6.6.11 8.0 Training

Include a section that states who needs training to the QP and the method of training required.

6.6.12 9.0 Attachments

Include a section that lists the attachment identifier (for example "Attachment A"), title (for example "Reviewer Concurrence Form"), and number of pages for each attachment. The document user may employ documentation formats different from those attached to/named in this procedure—as long as the substituted formats in use provide, as a minimum, the information required in the official forms developed by the procedure.

6.6.13 Pagination

During ER Project Document Signature Form initiation, an automatic ER catalog number is generated within the form. Reference this number in the footer of the document. Also, place the QP identifier ("QP-X.XX, RN", where "X.XX" is the specific number assigned to the QP by the DCC and "RN" is the revision number) and page numbers as appropriate in the footer on all pages of the QP (including attachments) as follows:

QP-X.XX, RN                                          Page __ of __
(ER2001-XXXX)

6.7   QP Peer Reviews

6.7.1   The **author** ensures that the QP (except for minor revisions to an existing QP) is reviewed and approved in accordance with QP-03.05, Peer Review Process.

**Note:**   It is the author's responsibility to acquire the peer review chair's signature on this ER Project Document Signature Form paper copy as he or she moves a document through the review and approval process steps defined in QP-03.05.

6.7.2   When satisfied that the QP is ready for approval, the **author** enters her or his signature and the date on the ER Project Document Signature Form and forwards the document package (i.e., the draft QP and the signature form) to the QPPL for review and approval.

6.7.3   When satisfied that the QP meets the requirements of this document, the **QPPL** enters his or her signature and the date on the ER Project Document Signature Form to indicate approval of the QP and forwards the document package to the ER Program Manager for review and approval.

6.7.4   When satisfied with the QP, the **ER Program Manager** signs and dates the ER Project Document Signature Form and returns the document package to the QPPL.

6.7.5   The **QPPL** submits both a hard copy and an electronic copy of the approved QP to the DCC and returns the document package to the author.

6.8   Issuing QPs

6.8.1   After completing step 6.7.4, the **DCC** enters the effective date on the QP cover page and in the appropriate block in the records log page, and provides a PDF electronic copy to the ER Project Web Master.

6.8.2   The **DCC** shall also provide the ER Project Web Master with an approved PDF electronic copy of an ICN, as appropriate for inclusion as a cover page for the affected procedure.

6.8.3   The **DCC** shall make the ER Project Web Master aware of all web links and forms as noted within the procedure.

6.8.4   The **ER Project Web Master** shall activate all links and forms as noted within the procedure and include all submitted ICNs, as appropriate. The **ER Project Web Master** shall then notify the QPPL that the QP has been placed on the ER Project web page

6.8.5   The **QPPL** notifies all ER Project participants of the issuance of a newly revised/developed QP.

6.8.6   The **DCC** processes the QP in accordance with QP-04.05, Document Control.

6.9   QP Deletion

6.9.1   To determine whether or not a QP is still needed, the **QPPL** notifies QP users when a QP deletion is requested. The notification does not need to be done formally (e.g., an informal e-mail or phone call is sufficient).

6.9.2   The **QPPL** notifies the DCC to delete the QP, unless notified by a user that the QP is still needed

6.9.3   The **DCC** processes the deleted QP in accordance with QP-04.05, Document Control.

6.10   Periodic QP Reviews

The **author** shall if appropriate review all quality procedures within their purview at least every two years to ensure that they meet the following:

- current methods and/or processes;

- current regulations, standards, laws, and/or requirements;

- any major changes to procedure format or requirements

6.10.1   Should the QP require to be revised the **author** will revise the QP and follow the requirements addressed in sections 6.3 and 6.4.

6.10.2   The **author** shall document the review and submit the documentation (e.g., a memorandum) to the ER Project Record Processing Facility.

6.11   Perform Lessons Learned

During the performance of work, **ER Project participants** shall identify, document and submit lessons learned, as appropriate in accordance with

QP-03.02, Lessons Learned, located at: http://erinternal.lanl.gov/home_links/Library_proc.htm.

## 7.0 RECORDS

The **author** is responsible for submitting the following records (processed in accordance with QP-04.04, Record Transmittal to the Records Processing Facility) to the Records Processing Facility.

7.1 A hardcopy of the approved QP

7.2 A signed copy of the ER Project Document Signature Form

7.3 A signed copy of the QP Interim Change Notice

7.4 An electronic copy of the approved QP

7.5 Correspondence addressing a QP's periodic review

## 8.0 TRAINING

8.1 All users of this QP are trained by reading the procedure. The **user** shall ensure the training is documented in accordance with QP-02.02, Personnel Orientation and Training, and is entered in the ER Project Training Database located at http://erinternal.lanl.gov/Training/Training.asp.

6.2 The **supervisor** will monitor the proper implementation of this procedure and ensure that relevant team members have completed all applicable training assignments in accordance with QP-02.02, Personnel Orientation and Training.

## 9.0 ATTACHMENTS

Attachment A: QP Interim Change Notice form and instructions (2 pages)

# Quality Procedure Interim Change Notice (ICN)

**Section 1: Description of Change** (Requestor completes) | 1. Document Catalog No.:

| 2. QP No.: | 3. Revision/Interim Change No.: (current) | 4. QP Title: |
|---|---|---|

5. Description of Change (Attach marked-up pages if necessary)

6. Attachments Modified, Added, or Removed: ☐ Yes ☐ No

7. Justification for ICN:

8. Requestor _____

       print name, then sign                                    (Date)

**Section 2: Evaluation and Approval** (QPPL and the Focus Area Leader completes)

9. Evaluation Remarks: (If none enter N/A)

10. Focus Area Leader _____

       print name, then sign                                  (Date)

11. QPPL _____

       print name, then sign                                  (Date)

QP-04.01

Los Alamos
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## Instructions for QP Interim Change Notice

**Section 1 – Description of Change** (Requestor Completes)

1. Enter the document catalog number

2. Record the procedure number.

3. Record the current revision and interim change number, as applicable (The Document Catalog Number shall be used as the ICN). The Document Catalog Number is obtained in accordance with QP-04.09, and is located on the ER Project internal homepage http://erinternal.lanl.gov.

4. Record the procedure title.

5. Describe the change. Provide marked-up copies of the procedure or attach additional sheets, as necessary.

6. Identify whether procedure attachments were modified, added, or removed. If "yes", identify the affected attachments.

7. Provide a clear and concise justification for the interim change notice.

8. Enter a printed and signed signature and date.

**Section 2 – Evaluation and Approval** (QPPL and Focus Area Leader Completes)

9. Record any evaluation remarks; if none, enter N/A.

10. Record the name of the responsible Focus Area Leader, sign and date.

11. Record the name of the QPPL, sign and date.